

available for one or more uses no occupational exposure shall be permitted for those uses.

(3) *Provisions of the proposed standard for Category II Potential Carcinogens.* Whenever the Secretary issues a Notice of Proposed Rulemaking to regulate a substance as a Category II Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, monitoring, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, recordkeeping and employee observation of monitoring as set forth in §1990.151, unless the Secretary explains why any or all such provisions are not appropriate; and

(ii) The model standard set forth in §1990.151 shall be used as a guideline; and

(iii) Worker exposure to Category II Potential Carcinogens will be reduced as appropriate and consistent with the statutory requirements on a case-by-case basis in the individual rulemaking proceedings. Any permissible exposure level so established shall be met primarily through engineering and work practice controls.

(b) *Emergency temporary standards (section 6(c) of the Act)*—(1) *General.* The Secretary may issue an Emergency Temporary Standard (ETS) for a Category I Potential Carcinogen in accordance with section 6(c) of the Act.

(2) *Provisions of the ETS.* (i) The ETS shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, methods of compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, signs and labels, recordkeeping and employee observation of monitoring, unless the Secretary explains why any or all such provisions are not appropriate.

(ii) The model standard set forth in §1990.152 shall be used as a guideline.

(iii) The permissible exposure limit shall be achieved through any prac-

ticable combination of engineering controls, work practice controls and respiratory protection.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

**§ 1990.143 General provisions for the use of human and animal data.**

Human and animal data which are scientifically evaluated to be positive evidence for carcinogenicity including the following policies shall be uniformly relied upon for the identification of potential occupational carcinogens. Arguments challenging the following provisions or their application to specific substances will be considered in individual rulemaking proceedings only if the evidence presented in support of the arguments meets the criteria for consideration specified in §1990.144 or §1990.145.

(a) *Positive human studies.* Positive results obtained in one or more human epidemiologic studies will be used to establish the qualitative inference of carcinogenic hazards to workers.

(b) *Positive animal studies.* Positive results obtained in one or more experimental studies conducted in one or more mammalian species will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that positive results obtained in mammalian species should not be relied upon will be considered only if evidence is presented which meets the criteria for consideration specified in §1990.144(c) or 1990.144(f).

(c) *Non-positive human studies.* Positive results in human or mammalian studies generally will be used for the qualitative identification of potential occupational carcinogens, even where non-positive results from human studies exist. Such non-positive results will be considered by the Secretary only if the studies or results meet the criteria set forth in §1990.144(a).

(d) *Non-positive animal studies.* Positive results in one or more mammalian studies will be used for the qualitative identification of potential occupational carcinogens, even where non-positive studies exist in other mammalian species. Where non-positive and positive results exist in studies in the same species, the non-positive results will be evaluated.

(e) *Spontaneous tumors.* Positive results in human or mammalian studies for the induction or acceleration of induction of tumors of a type which occurs “spontaneously” in unexposed individuals will be used for the qualitative identification of potential occupational carcinogens.

(f) *Routes of exposure.* (1) Positive results in studies in which mammals are exposed via the oral, respiratory or dermal routes will be used for the qualitative identification of potential occupational carcinogens, whether tumors are induced at the site of application or distant sites.

(2) Positive results in studies in which mammals are exposed via any route of exposure and in which tumors are induced at sites distant from the site of administration will be used for the qualitative identification of potential occupational carcinogens.

(3)(i) Positive results in mammalian studies in which tumors are induced only at the site of administration, in which a substance or mixture of substances is administered by routes other than oral, respiratory or dermal, will be used as “concordant” evidence that a substance is a potential occupational carcinogen.

(ii) Arguments that such studies should not be relied upon will be considered only if evidence which meets the criteria set forth in § 1990.144(b) is provided.

(g) *Use of high doses in animal testing.* Positive results for carcinogenicity obtained in mammals exposed to high doses of a substance will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that such studies should not be relied upon will be considered only if evidence which meets the criteria set forth in § 1990.144(d) is provided.

(h) *“Threshold” or “No-effect” Levels.* No determination will be made that a “threshold” or “no-effect” level of exposure can be established for a human population exposed to carcinogens in general, or to any specific substance.

(i) *Benign tumors.* Results based on the induction of benign or malignant tumors, or both, will be used to establish a qualitative inference of carcinogenic hazard to workers. Arguments that substances that induce benign tu-

mors do not present a carcinogenic risk to workers will be considered only if evidence that meets the criteria set forth in § 1990.144(e) is provided.

(j) *Statistical evaluation.* Statistical evaluation will be used in the determination of whether results in human, animal or short-term studies provide positive evidence for carcinogenicity, but will not be the exclusive means for such evaluation.

(k) *Carcinogenicity of metabolites.* A substance which is metabolized by mammals to yield one or more potential occupational carcinogens will itself be identified and classified as a potential occupational carcinogen, whether or not there is direct evidence that it induces tumors in humans or experimental animals. Evidence for such metabolism will normally be derived from *in vivo* studies in mammals. In appropriate circumstances, evidence may be derived from *in vitro* studies of mammalian tissues or fractions thereof. Arguments that evidence from *in vivo* metabolic studies in mammals is not relevant to the inference of carcinogenic hazard to humans will be considered only if such evidence meets the criteria set forth in § 1990.144(c).

[45 FR 5282, Jan. 22, 1980; 45 FR 43405, June 27, 1980]

#### § 1990.144 Criteria for consideration of arguments on certain issues.

Arguments on the following issues will be considered by the Secretary in identifying or classifying any substance pursuant to this part, if evidence for the specific substance subject to the rulemaking conforms to the following criteria. Such arguments and evidence will be evaluated based upon scientific and policy judgments.

(a) *Non-positive results obtained in human epidemiologic studies.* Non-positive results obtained in human epidemiologic studies regarding the substance subject to the rulemaking or to a similar or closely related substance will be considered by the Secretary only if they meet the following criteria:

*Criteria.* (i) The epidemiologic study involved at least 20 years’ exposure of a group of subjects to the substance and at least 30 years’ observation of the subjects after initial exposure;